UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

JUN 2 9 2018

OFFICE OF THE CHIEF FINANCIAL OFFICER

The Honorable Kenneth Calvert Chairman, Subcommittee on Interior. Environment and Related Agencies Committee on Appropriations House of Representatives Washington, D.C. 20515

The Honorable Lisa Murkowski Chairman, Subcommittee on Interior, Environment and Related Agencies Committee on Appropriations United States Senate Washington, D.C. 20510

The Honorable Betty McCollum Ranking Member, Subcommittee on Interior, Environment and Related Agencies Committee on Appropriations House of Representatives Washington, D.C. 20515

The Honorable Tom Udall Ranking Member, Subcommittee on Interior, Environment and Related Agencies Committee on Appropriations United States Senate Washington, D.C. 20510

Dear Chairmen Calvert and Murkowski and Ranking Members McCollum and Udall:

Enclosed please find the U.S. Environmental Protection Agency's Report to Congress on the Implementation of EPA's Plan to Increase Access to Results of EPA-Funded Scientific Research, as required in the explanatory language accompanying the Consolidated Appropriations Act of 2018 (P.L. 115-141).

[EPA] released its Plan to Increase Access to Results of EPA Funded Scientific Research on November 29, 2016. The Committees urge the Agency to continue its efforts towards full implementation of the plan, and directs the Agency to provide an update on its efforts within 60 days of enactment of this Act.

The Report provides an update to Congress on the EPA's continuing efforts to implement its Plan and how the agency is enabling scientists to comply successfully with the requirements established in the Plan and its related activities.

If you have further questions, please contact me or Ed Walsh of my staff at Walsh.Ed@epa.gov or (202) 564-4594.

Sincerely,

Holly W. Greaves

Chief Financial Officer

Enclosures

- 1. Implementation of EPA's Plan to Increase Access to Results of the EPA-Funded Scientific Research A Report to Congress (2018)
- 2. U.S. EPA Forum on Increasing Public Access to EPA Scientific Research Charter
- Public Access Forum Workgroup Charge Public Access Forum Publications Workgroup, July 5, 2017
- 4. Public Access Forum Workgroup Charge Public Access Forum Training Workgroup, September 28, 2017
- 5. Public Access Forum Workgroup Charge Public Access Forum Data Workgroup, July 5, 2017
- 6. Public Access Forum Workgroup Charge Public Access Forum Extramural Scientific Research Workgroup, July 5, 2017
- 7. EPA-Funded Research Publication Submissions in PubMed Central (PMC), Implementation Plan, Version 1, 2 January 2018

Implementation of EPA's Plan to Increase Access to Results of EPA-Funded Scientific Research

A Report to Congress - 2018

Environmental Protection Agency

Office of Research and Development

Office of the Science Advisor

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- 1. <u>Purpose:</u> This report is responsive to Congressional language included in the 2018 Omnibus Appropriations.
 - [EPA] released its Plan to Increase Access to Results of EPA Funded Scientific Research on November 29, 2016. The Committees urge the Agency to continue its efforts towards full implementation of the plan, and directs the Agency to provide an update on its efforts within 60 days of enactment of this Act.¹
- 2. Summary: EPA is continuing to implement its Plan to Increase Access to Results of EPA-Funded Scientific Research (Plan).² The Plan was completed and released in November 2016 and included implementation in three stages. Phase 1 had been implemented on January 1, 2016 and included all publications and underlying data from intramural scientists within the Agency's Office of Research and Development (ORD). To implement phases 2 and 3 of the Plan, EPA established an Agency-wide forum. The Forum on Increasing Public Access to EPA Research was chartered as a standing group of the EPA Science Technology Policy Council on April 17, 2017. Phase 2 implementation began January 1, 2018 and covered access to the publications and underlying data of non-ORD intramural scientists. Implementation plans for non-ORD intramural datasets (Phase 2) and EPA extramurally funded publications and underlying data (Phase 3) are well underway and targeted for 2018. In addition, a training working group is developing materials to enable Agency scientists to successfully comply with the requirements established in the implementation plans.
- 3. <u>Background:</u> On February 22, 2013, the White House Office of Science and Technology Policy (OSTP) issued a memorandum entitled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo). The memorandum directs Federal departments and agencies that spend more than \$100 million per year on research and development (which includes EPA) "to develop...a plan...to increase public access to peer-reviewed, scientific research publications and research data resulting from agency-funded scientific research." The fundamental notion underlying this memorandum is that the results of Federally funded scientific research should be available to the public, the scientific community, and industry to the greatest extent feasible consistent with applicable law and policy; agency mission; resource constraints; U.S. national, homeland, and economic security; and the specific objectives of the memorandum.

In response, the EPA developed a plan that describes the steps the Agency will take to further increase access to the results of EPA-funded scientific research, consistent with the objectives of the OSTP Memo.

The [EPA] Plan prospectively covers peer-reviewed scientific research publications in scholarly journals and underlying digital research data that result from EPA-funded research. The Plan does not apply to research publications or research data generated from scientific research conducted prior to the implementation of the Plan... EPA will create a Forum on Increasing Public Access to EPA Research to implement the Plan.

¹ Text from the 2018 Omnibus Appropriations.

² For more information, see: https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research.

[The Forum] will provide cross-Agency coordination to identify and recommend to the Administrator policies, procedures, infrastructure, and training in support of the Plan. Approved recommendations will be implemented by EPA programs and regional offices. Implementation will be completed in three phases.

On April 30, 2018, the *Federal Register* published a proposed rule by EPA titled: Strengthening Transparency in Regulatory Science. EPA is currently soliciting comments on the Notice of Proposed Rulemaking. The summary of the proposed rule states:

...when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publically available in a manner sufficient for independent validation.

EPA will seek to integrate forthcoming work with respect to the aforementioned Notice of Proposed Rulemaking into the Plan where relevant and appropriate.

4. Phase 1 Implementation: Phase 1 was implemented prior to the final approval of the EPA Plan. ORD committed to implementing formal Scientific Data Management procedures, and public release for data supporting peer reviewed intramural research published on or after October 1, 2015.³ Since then, ORD has actively worked to ensure that research publications are accessible on PubMed Central (PMC). ORD is using the EPA's *ScienceHub* as the catalog and repository for datasets underlying these publications. ORD has integrated its electronic clearance system to track and link publications with PMC and *ScienceHub*.

Figure 1 documents steady progress implementing Phase 1 of the EPA plan. During the period metrics were available, 72% of datasets associated with publications (368 out of 508) were made available. That percentage has been increasing over time with 85% (62 out of 73) made available in the second quarter of FY 2018. The number of publications uploaded into PMC has also been increasing over time. Currently, the publications reported by this metric underestimate the publications that have been made available to the public. This metric captures only automated submissions to PMC, which began in October 2017. Publications submitted prior to that date, publications in PMC indexed journals, and publications in open journals are therefore not included in the statistics shown in **Figure 1**.

Ongoing efforts will increase the percentage of datasets associated with publications made available and improve our ability to accurately count the publications made available to the public. Lessons learned from the efforts to measure implementation of Phase 1 will be applied to measuring implementation of Phases 2 and 3.

³ Memo: Requirements for ORD Intramural Data Publication Begin February 2016. J. Blancato. Dated: January 29, 2016.

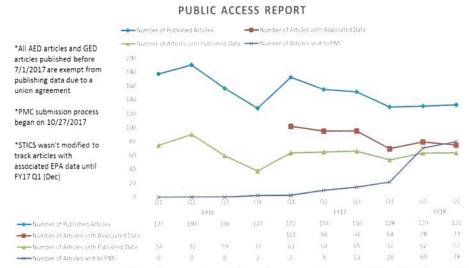


Figure 1: Access to Office of Research and Development Intramural Peer Reviewed Publications and Underlying Datasets - Fiscal Years 2016-2018.

- 5. Forum on Increasing Public Access to EPA Research (Forum): The Plan called for the development of a cross-Agency Public Access Forum that would report to EPA's Science and Technology Policy Council (STPC). The Forum on Increasing Public Access to EPA Research (Forum) charter was approved by the STPC and signed by the EPA Science Advisor on April 17, 2017 (Attachment A). The purpose of the Forum is to provide cross-Agency coordination and oversight for the implementation of the Plan. In addition, the Forum is both assessing infrastructure needs/options and developing consistent policies, procedures, guidelines, training, and metrics. Co-chairs from ORD and the Office of Environmental Information were identified as well as members representing the Office of Administration and Resources Management, Office of Air and Radiation, Office of Chemical Safety and Pollution Prevention, Office of the Chief Financial Officer, Office of Enforcement and Compliance Assurance, Office of the General Counsel, Office of Land and Emergency Management, Office of Policy, Office of Water, and two Regional Offices. The Forum meets monthly. The Forum established the following working groups:
 - Public Access Forum Publications Workgroup Charge (Attachment B) This
 workgroup is charged with developing an Agency-wide implementation plan for the
 submission of author manuscripts or indexed journal articles into PMC.
 - Public Access Forum Training Workgroup Charge (Attachment C) This workgroup is charged with developing and disseminating training materials to EPA employees and extramural researchers to inform them of the Agency's public access requirements and to assist them in submitting manuscripts to PMC and underlying datasets to a qualified data repository.
 - Public Access Forum Data Workgroup Charge (Attachment D) This workgroup is developing an Agency-wide process to make available research data underlying EPAfunded peer reviewed research publications.
 - Public Access Forum Extramural Scientific Research Workgroup Charge (Attachment
 E) This workgroup is charged with implementing Phase 3 of the Plan. This includes

developing standard language needed for including public access requirements into extramural funding vehicles (e.g., grants, contracts, cooperative agreements).

The Forum working groups typically meet weekly to establish implementation procedures within the target dates in the Plan. Draft working group products are first approved by the Forum before being distributed for concurrence by the STPC. Upon concurrence, the completed products are transmitted by the EPA Science Advisor across EPA.

6. Phase 2 Implementation: Implementation of EPA non-ORD intramural research requires developing separate implementation plans for publications and for data. The implementation plan for all intramural publications (including non-ORD authored manuscripts) was completed and disseminated by the Science Advisor on March 29, 2018 (Attachment F). Under the implementation plan:

EPA researchers, or their programs and regions, will deposit final accepted, journal article manuscripts (i.e., that have incorporated peer review edits and any needed changes), hereafter referred to as the author manuscript, into PMC (unless submitted by an indexed journal). To ensure the timeliness of these submissions, EPA will work toward utilizing the NIH Manuscript Submission System (NIHMS) no later than 30 days after the date of final publication. To clarify the relationship between PMC and NIHMS, PMC is the repository for publications, and NIHMS is the mechanism/procedures by which manuscripts are entered.

All EPA programs and regions will establish practices to identify and track author manuscript submissions to NIHMS. At a minimum, EPA programs and regions will track the number of published articles, the number of manuscripts submitted to NIHMS, and the number of manuscripts available on PMC.

Researchers in non-ORD programs and regions are required to deposit into NIHMS all author manuscripts accepted for publication starting January 1, 2018. [ORD intramural research manuscripts have been entered into NIHMS since September 28, 2017.]

The target date for implementation of access to non-ORD intramural datasets underlying peer-reviewed publications is 2018. The Public Access Forum Data Working Group has drafted its implementation plan, which Is currently under review by the Forum. Once approved by the Forum, it will be distributed to the STPC for concurrence. The data implementation plan will likely be completed and distributed across EPA during the fourth quarter of Fiscal Year 2018.

Because all of the implementation plans are forward looking, *i.e.*, prospectively covering publications and underlying datasets, after the implementation plans have been completed, the first attempt to measure implementation of Phase 2 will take place in 2019.

7. Phase 3 Implementation: The target date for implementation of extramural peer-reviewed publications and underlying data is 2018. The data and publications working groups are considering requirements for extramural agreements. In addition, the Public Access Forum Extramural Scientific Research Working Group is developing language for new contracts, cooperative agreements, and grants that will be inserted into extramural agreements. Once

Implementation of EPA's Plan to Increase Access to Results of EPA Funded Scientific Research

completed, standard language will appear in new extramural funding announcements. Public access to the scientific peer-reviewed publications and underlying data sets generated from these new extramural agreements will be covered by the new language.

- **8.** <u>Training:</u> The Forum members recognized that developing implementation plans to increase access to EPA-funded research needed supplemental training materials to inform intramural and extramural scientists of the requirements established by the plans. Training materials to date focus on the completed implementation plan for intramural publications. These include:
 - An awareness video that informs EPA employees about the requirement to post scientific research journal manuscripts that are published starting January 1, 2018, to PMC. The video is available on the EPA YouTube channel and imbedded on the EPA's Public Access intranet page.
 - An "EPA Public Access Submission and Review Guide for Publications to PMC," which includes step-by-step, EPA-specific instructions on uploading author manuscripts to PMC.

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United States Environmental Protection Agency Forum on Increasing Public Access to EPA Scientific Research Charter

1. PURPOSE AND SCOPE

The Forum on Increasing Public Access to EPA Research (Forum) is established under the US Environmental Protection Agency (EPA or the Agency) Science and Technology Policy Council (STPC). The purpose of the Forum is to implement the Agency's *Plan to Increase Access to the Results of EPA-Funded Scientific Research* (Plan)¹ by:

- · Assessing infrastructure needs and options for deployment;
- Identifying and developing consistent policies, procedures, training, guidelines (e.g., for Agency researchers and Agency research award recipients);
- Develop strategies (e.g., for sustainable funding and infrastructure) to implement the Plan;
- · Developing metrics to evaluate compliance with the Plan;
- · Providing cross-Agency coordination in support of the Plan; and
- Providing oversight for the implementation of the Plan.

The Forum will support existing activities and enhance consistency across the Agency by adopting best practices that effectively and efficiently increase public access to EPA-funded scientific research and advance plan implementation². Upon request by the EPA Science Advisor or the STPC, the Forum also will develop additional reports or other products related to the Plan. The Office of the Science Advisor (OSA) and Office of Environmental Information (OEI) lead and support Forum activities and efforts.

2. MEMBERSHIP

The Forum will consist of approximately fifteen members, including the Chair (or Co-Chairs). One member will come from each of the following Agency organizations:

- · Office of Administration and Resources Management (OARM),
- Office of Air and Radiation (OAR),
- · Office of Chemical Safety and Pollution Prevention (OCSPP),
- Office of the Chief Financial Officer (OCFO),
- Office of Enforcement and Compliance Assurance (OECA),
- Office of Environmental Information (OEI),
- · Office of General Counsel (OGC),
- · Office of Land and Emergency Management (OLEM),
- Office of Policy (OP),
- · Office of Research and Development (ORD) and
- · Office of Water (OW).
- Lead Region for OEI
- Lead Region for ORD

¹ The Plan can be accessed at: https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research

² The Forum is neither a part of, nor does it replace or supplement, existing Agency and individual Program or Regional Office management or their operational procedures and processes.

Forum members will provide oversight for and report on the implementation of the Plan within their office or in each of the ten Regions in the case of the Regional members.

STPC members from these Offices may nominate representatives as they determine appropriate. Forum members will have oversight of the Plan's implementation in their program. Experience with science research publication; scientific research administration; or planning, budgeting, and accountability for scientific research is desirable. Nominees must have or be able to gain knowledge of the intramural and extramural research, publications, and data generated across their office or the Regions. As needed, Forum members should be able to identify and obligate resources to implement the Plan within their respective organizations and to participate in specific Forum activities. Membership appointments will be for two years. After two years, the STPC member may re-nominate the same Forum member or nominate a new member.

3. ORGANIZATION

Reporting/Authority

The Forum reports and makes recommendations to the STPC, which is chaired by the Agency Science Advisor. As appropriate, the Science Advisor will take recommendations from the STPC to the Administrator.

Officer(s)

The Chair (or Co-Chairs) for the Forum are appointed by the Science Advisor. The Forum Chair (or Co-Chairs) will serve as the liaison(s) to the STPC.

Forum Coordinators

The Forum has two Coordinators designated by OSA and OEI, who report to their respective office's management. The Coordinators function as the Operating Officers of the Forum to manage its product development and assigned resources (i.e., other technical staff and funds) to assure that technical, logistical, and operational needs are met.

4. OPERATIONS

Meetings

The Forum will meet monthly, if needed, to implement the Plan within the timeline given in the Plan's Section XI. Once the plan is implemented, the Forum should meet at least quarterly. These meetings can be virtual or face-to-face when practical. Agendas will be distributed to the members before each meeting, along with any materials to be reviewed at that meeting. The Forum will strive to reach consensus during its deliberations. If consensus cannot be reached, the Forum Chair (or Co-Chairs) will work to resolve the issue and develop a path forward in coordination with OSA and OEI prior to elevating the issue to the STPC.

Activities and Workgroups

The Forum will determine the activities needed to fully implement the Plan, consistent with items given in the Plan's Section XI and Appendix C. Workgroups may be established to focus on specific aspects of the Plan (e.g., extramural research, funding, training). A specific charge will be developed for each workgroup (see OSA's SOP for Establishing a STPC

*Project Charge*³). After the Forum reviews the draft charge, it will be sent for approval to the STPC. Participants for the workgroups will be provided by staff from the Offices and Regions that make up the Forum with assistance from the Coordinators.

Products

Products (e.g., policy, strategy, guidance, procedures) developed for or by the Forum or its workgroups are expected to meet the Plan and/or the project charge goals. Review and clearance of these products will follow the OSA SOP for Product Review, Concurrence, Clearance, Distribution/Dissemination⁴. The STPC will concur on whether the products, including any recommendations, should be adopted by the Agency.

Ongoing Assessments and Annual Action Agenda

The Forum will provide updates to the STPC, OSTP and OMB on implementation of this plan in January and July of each year for the first two years after the plan is approved. The Chair (or Co-Chairs) and Coordinators are responsible for developing an Action Agenda for the year ahead that conforms to the purpose and scope outlined in this Charter. To the extent known, estimated resource requirements should be included for future activities.

Evaluations

The Forum will review and recommend amendments of the Plan, and its implementation, to the STPC and SA as needed and in consultation with OSTP and OMB.

Amending Charter

Amendments to the Charter can be proposed by the Science Advisor or an STPC Member, with approval by the STPC.

Kobert Kawlunk Robert J. Kavlock, Ph.D. EPA Science Advisor

4/17/2017

Date

³ Standard Operating Procedure for Establishing a STPC Project Charge is available at https://intranet.ord.epa.gov/sites/default/files/media/OSA/osa_sop_establishing_a_stpc_project_charge.pdf.

⁴ Standard Operating Procedure for Product Review, Concurrence, Clearance, Distribution/Dissemination is available at

 $https://intranet.ord.epa.gov/sites/default/files/media/OSA/osa_sop_product_review_concurrence_clearance_distribution_dissemination.pdf.$

Public Access Forum Workgroup Charge

Title: Public Access Forum Publications Workgroup

Standing Group: Forum on Increasing Public Access Forum to EPA Scientific Research

Approval Date: July 5, 2017

1. Introduction:

Goal and Purpose:

The Public Access Forum Publications Workgroup is charged with developing an Agency-wide process and implementation plan that recommends practices to facilitate the submission of prospective EPA-funded, peer-reviewed intramural and extramural scientific research publications to NIH PubMed Central (PMC).

Background:

The White House Office of Science and Technology Policy issued a memorandum "Increasing Access to the Results of Federally Funded Scientific Research" in February 2013. In response, EPA released its "Plan to Increase Access to Results of EPA-Funded Scientific Research" (Public Access Plan) in November 2016.

Problem Statement/Agency Need:

One of the commitments made in the Agency's Public Access Plan is the submission of EPA-funded scientific, peer-reviewed research publications to NIH's PMC, thereby allowing the public to read, download, and analyze in digital form publications arising from EPA-funded research.

2. Expected Products:

The expected product from the Publications Workgroup will be an implementation plan identifying the process(es) by which EPA-funded, peer-reviewed, intramural (initially – see timeline) and extramural (subsequently) scientific research publications will be submitted to NIH's PMC. The implementation plan will include each program and regional office's mechanism (e.g., platform) and process for submitting its intramural publications to PMC. In addition, in coordination with the Extramural Scientific Research Workgroup, the plan will describe each program and regional office's process for requiring its extramural researchers to submit their publications to PMC.

3. Implementation Approach:

The Publications Workgroup will develop recommended practices that the Agency will undertake to implement the publication elements of the Public Access Plan. This may include aspects related to program- or region-specific considerations, as well as aspects that apply Agency-wide. It may also include near-term actions for intramural research and longer-term actions for extramural research.

The Forum will be establishing a Training and Tracking Workgroup that will develop "corporate" training materials on the use of the relevant products developed by the Forum. These materials

may be used by program and regional offices with their employees (Initially) and extramural researchers (subsequently). Each program and regional office will develop and disseminate its own training materials, supplementing the corporate training materials as it deems needed. When offices choose to employ a common platform and process, the offices will be encouraged to develop and disseminate joint training materials.

Based on input provided by the program and regional offices, the Training and Tracking Workgroup will collect tracking results and perform compliance evaluations with the Public Access Plan.

Once the Public Access Forum has approved the Publications Workgroup's implementation plan, the workgroup will sunset as a distinct entity. The Forum will oversee the implementation of the workgroup's approved plan.

4. Review and Clearance Approach:

The workgroup's implementation plan will first be approved by the Public Access Forum for submission to the STPC for approval.

5. Timeline:

The target date for the workgroup to submit its implementation plan for intramural publications for review by the Public Access Forum is October, 2017. The target date for the workgroup to submit its implementation plan for extramural publications for review by the Public Access Forum is June, 2018.

6. Resources:

Anticipated resources are primarily staff time from the Agency's program and regional offices, supplemented by coordination support from OSA and OEI. Recommended practices, however, may lead to the identification of potential Agency-wide or program/region-specific resource needs to support infrastructure and/or training activities.

7. Workgroup Members:

The composition of the Workgroup will be determined by the members of the Public Access Forum. Forum members may nominate themselves or personnel from their organizations to the Workgroup.

8. References

Memorandum for the Heads of Executive Departments and Agencies, Subject: Increasing Access to the Results of Federally Funded Scientific Research, Office of Science and Technology Policy, February 22, 2013. https://obamawhitehouse.archives.gov/blog/2016/02/22/increasing-access-results-federally-funded-science.

Plan to Increase Access to Results of EPA-Funded Scientific Research, US Environmental Protection Agency, November 29, 2016. https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research.

Forum on Increasing Public Access to EPA Scientific Research Charter, US Environmental Protection Agency, April 17, 2017.

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Public Access Forum Workgroup Charge

Title: Public Access Forum Training Workgroup

Standing Group: Forum on Increasing Public Access to EPA Scientific Research

Approval Date: September 28, 2017

1. Introduction:

Goal and Purpose:

The Public Access Forum Training Workgroup is charged with the developing and disseminating training materials for EPA employees and extramural researchers on the use of the products and fulfillment of procedures developed under the Forum, "e.g., how to submit a publication to PubMed Central (PMC), how to upload the data underlying a publication into the Environmental Dataset Gateway."

Background:

The White House Office of Science and Technology Policy issued a memorandum "Increasing Access to the Results of Federally Funded Scientific Research" in February 2013. In response, EPA released its "Plan to Increase Access to Results of EPA-Funded Scientific Research" in November 2016.

Problem Statement/Agency Need:

The Agency's Public Access Plan commits to providing training for current and new Agency scientists, as well as extramural scientists funded, wholly or in part, by EPA.

2. Expected Products:

The expected products from the Training Workgroup will be user-friendly "corporate" training materials for EPA employees and extramural researchers on the use of the products and procedures developed under the Forum.

3. Implementation Approach:

The Training Workgroup, assisted by contractor support, will develop and disseminate corporate training materials for EPA employees and extramural researchers on the use of the products developed under the Forum and the relevant requirements. The workgroup will work with the Publications, Data, and Extramural Scientific Research Workgroups in developing the training materials.

The corporate training materials will serve as a resource as each program and regional office develops and disseminates its own training materials. When offices choose to employ a common process, they will be encouraged to develop and disseminate joint training materials.

The Training workgroup, assisted by contractor support, will also help offices conduct training if requested.

The Training Workgroup will sunset when the Public Access Forum decides that the Forum itself can perform the activities of the workgroup.

4. Review and Clearance Approach:

The workgroup's implementation plan will first be approved by the Public Access Forum before submission to the STPC for approval.

5. Timeline:

- a. The target date for the workgroup to complete corporate training materials related to the submission of intramural scientific research publications to PMC is December 15, 2017.
- b. The target date for the workgroup to complete corporate training materials related to the submission of the data underlying intramural scientific research publications submitted to PMC is October 2018.
- c. The target date for the workgroup to complete training materials related to making EPAfunded extramural scientific research publications and the underlying data publicly available is December 2018.

6. Resources:

Anticipated resources are primarily staff time from the Agency's program and regional offices, supplemented by coordination support from OSA and OEI.

7. Workgroup Members:

The composition of the workgroup will be determined by the members of the Public Access Forum. Forum members may nominate themselves or personnel from their organizations to the workgroup.

8. References

Memorandum for the Heads of Executive Departments and Agencies, Subject: Increasing Access to the Results of Federally Funded Scientific Research, Office of Science and Technology Policy, February 22, 2013. https://obamawhitehouse.archives.gov/blog/2016/02/22/increasing-access-results-federally-funded-science.

Plan to Increase Access to Results of EPA-Funded Scientific Research, US Environmental Protection Agency, November 29, 2016. https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research.

Forum on Increasing Public Access to EPA Scientific Research Charter, US Environmental Protection Agency, April 17, 2017.

Public Access Forum Workgroup Charge

Title: Public Access Forum Data Workgroup

Standing Group: Forum on Increasing Public Access to EPA Scientific Research

Approval Date: July 5, 2017

1. Introduction:

Goal and Purpose:

The Public Access Forum Data Workgroup is charged with developing an Agency-wide process and implementation plan to enable the prospective research data underlying EPA-funded, peer-reviewed intramural and extramural scientific research publications to be made publicly available.

Background:

The White House Office of Science and Technology Policy issued a memorandum "Increasing Access to the Results of Federally Funded Scientific Research" in February 2013. In response, EPA released its "Plan to Increase Access to Results of EPA-Funded Scientific Research" (Public Access Plan) in November 2016.

Problem Statement/Agency Need:

One of the commitments made in the Agency's Public Access Plan is to give the general public access to the research data underlying EPA-funded scientific research publications within 30 days of the publication being made publicly available through PMC.

2. Expected Products:

The expected product from the Data Workgroup will be an implementation plan identifying the processes, infrastructure needs, and funding requirements for making the data underlying EPA-funded, intramural (initially – see timeline in Public Access Plan) and extramural (subsequently) scientific research publications publicly accessible.

Assuming a common approach for all program and regional offices with respect to intramural scientific research data, the implementation plan will include identifying processes, infrastructure needs, and funding requirements surrounding expanding EPA's metadata catalog, the Environmental Dataset Gateway (EDG), and ORD's ScienceHub application, as well as describing how the existing ORD Scientific Data Management Plan (SDMP) Guidance will be revised to enable its implementation Agency-wide.

Should a program or regional office choose to follow its own approach to making its intramural scientific research data available, the implementation plan will (a) include identifying the office's or region's processes, infrastructure needs, funding requirements, and SDMP guidance and (b) describe how the program or regional office's approach relates to EPA's metadata catalog, the Environmental Dataset Gateway (EDG), and data.gov.

Assuming a common approach for all program and regional offices with respect to extramural scientific research data, the Data Workgroup will work with the Extramural Scientific Research Workgroup to develop SDMP guidance for extramural researchers and requirements for these researchers to ensure their data are publicly accessible.

3. Implementation Approach:

The Data Workgroup will develop recommended practices that the Agency will undertake to implement the data elements of the Public Access Plan. This may include aspects related to program- or region-specific considerations, as well as aspects that may apply Agency-wide. It may also include near-term actions for intramural research and longer-term actions for extramural research.

Assuming a common approach for all program and regional offices, the expected products would be implemented through working with (1) the EDG and ScienceHub programs, as well as other parts of the Agency to implement the technical aspects of the implementation plan, and (2) the Forum's Training and Tracking Workgroup, which the Forum will establish at a future date. The Training and Tracking Workgroup will develop and disseminate "corporate" training materials for EPA employees (initially) and extramural researchers (subsequently) on the use of the processes and systems developed and expanded under the Forum.

Should a program or regional office choose its own mechanism and process to make its data available, each program and regional office will develop and disseminate its own training materials, supplementing the corporate training materials as it deems needed. When offices choose to employ a common mechanism and process, the offices will be encouraged to develop and disseminate joint training materials.

Based on input provided by the program and regional offices, the Training and Tracking Workgroup will collect tracking results and perform compliance evaluations with the Public Access Plan.

Once the Data Workgroup's implementation plan has been approved by the Public Access Forum, the workgroup will sunset as a distinct entity. The Forum will oversee the implementation of the workgroup's approved plan.

4. Review and Clearance Approach:

The workgroup's implementation plan will first be approved by the Public Access Forum for submission to the STPC for approval.

5. Timeline:

The target date for the workgroup to submit its implementation plan for the data underlying intramural scientific research publications for review by the Public Access Forum is March, 2018. The target date for the workgroup to submit its implementation plan for the data underlying extramural scientific research publications for review by the Public Access Forum is September, 2018.

6. Resources:

Anticipated resources are primarily staff time from the Agency's program and regional offices, supplemented by coordination support from OSA and OEI. Recommended practices, however, may lead to the identification of potential Agency-wide or program/region-specific resource needs to support infrastructure and/or training activities.

7. Workgroup Members:

The composition of the Workgroup will be determined by the members of the Public Access Forum. Forum members may nominate themselves or personnel from their organizations to the Workgroup.

8. References

Memorandum for the Heads of Executive Departments and Agencies, Subject: Increasing Access to the Results of Federally Funded Scientific Research, Office of Science and Technology Policy, February 22, 2013. https://obamawhitehouse.archives.gov/blog/2016/02/22/increasing-access-results-federally-funded-science.

Plan to Increase Access to Results of EPA-Funded Scientific Research, US Environmental Protection Agency, November 29, 2016. https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research.

Forum on Increasing Public Access to EPA Scientific Research Charter, US Environmental Protection Agency, April 17, 2017.

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Public Access Forum Workgroup Charge

Title: Public Access Forum Extramural Scientific Research Workgroup

Standing Group: Forum on Increasing Public Access Forum to EPA Scientific Research

Approval Date: July 5, 2017

1. Introduction:

Goal and Purpose:

The Public Access Forum Extramural Scientific Research Workgroup is charged with developing language as needed for grants, contracts, cooperative agreements, and perhaps other funding instruments between EPA and extramural scientific researchers regarding the submission of prospective EPA-funded, peer-reviewed scientific research publications to NIH PubMed Central (PMC) and posting the underlying digital data from the publications to a publicly accessible platform.

Background:

The White House Office of Science and Technology Policy issued a memorandum "Increasing Access to the Results of Federally Funded Scientific Research" in February 2013. In response, EPA released its "Plan to Increase Access to Results of EPA-Funded Scientific Research" (Public Access Plan) in November 2016.

Problem Statement/Agency Need:

One of the commitments made in the Agency's Public Access Plan is development of relevant language for EPA-funded extramural solicitations (e.g., contracts, grants and cooperative agreements) requiring that journal publications from EPA-funded research are made available to the public no later than 12-months after the date of publication. In addition, the Public Access Plan includes the requirement that the digital data underlying the publications be made accessible to the public within 30 days of posting of a scientific research publication.

2. Expected Products:

Lead by OARM with guidance from OGC, the expected product from the Extramural Scientific Research Workgroup will be standard language to be included in all relevant funding agreements between EPA and extramural scientific researchers (e.g., contracts, grants, and cooperative agreements) that states the requirements for public accessibility to EPA-funded research publications and the associated digital data.

To assist extramural researchers, the Extramural Scientific Research Workgroup will develop template Scientific Data Management Plans (SDMPs) for extramural research data. The Extramural Scientific Research Workgroup will work with the Publications Workgroup to develop a process for tracking publications generated from extramural research projects and with the Data Workgroup on requirements for how extramural researchers will make the digital data that underlies their publications publicly accessible.

To produce training materials for extramural researchers on development of SDMPs, posting of research publications and data, and on a method for compliance monitoring, the Extramural Scientific Research Workgroup will work with the Training and Tracking Workgroup.

3. Implementation Approach:

Once the Extramural Scientific Research Workgroup has developed the language for funding agreements, OARM will need to ensure the language is included in any extramural solicitations that involve EPA-funded scientific research that might possibly lead to journal publications.

Additionally, once the Public Access Forum has approved the language developed by the Extramural Scientific Research Workgroup, the workgroup will sunset as a distinct entity. The Public Access Forum will oversee the implementation of the workgroup's approved language.

The Forum will be establishing a Training and Tracking Workgroup that will develop "corporate" training materials on the use of the relevant products developed by the Forum. Each program and regional office will develop and disseminate its own training materials, supplementing the corporate training materials as it deems needed. When offices choose to employ a common platform and process, the offices will be encouraged to develop and disseminate joint training materials.

Training materials will be developed to inform extramural researchers about the requirements for SDMPs and the posting of research publications and digital data. Compliance will be monitored according to the protocols developed with the Training and Tracking Workgroup.

4. Review and Clearance Approach:

The workgroup's implementation plan will first be approved by the Public Access Forum for submission to the STPC for approval.

5. Timeline:

The target date for the workgroup to submit its implementation plan for review by the Public Access Forum is June, 2018. The Public Access Plan's timeline for implementation calls for including relevant language in EPA-funded extramural solicitations by 2018.

6. Resources:

Anticipated resources are primarily staff time from the Agency's program and regional offices, supplemented by coordination support from OSA and OEI. The Extramural Scientific Research Workgroup will need to include members from OARM and OGC who are familiar with contracts, grants, cooperative agreements, and other scientific research funding instruments.

7. Workgroup Members:

The composition of the Workgroup will be determined by the members of the Public Access Forum. Forum members may nominate themselves or personnel from their organizations to the Workgroup.

8. References

Memorandum for the Heads of Executive Departments and Agencies, Subject: Increasing Access to the Results of Federally Funded Scientific Research, Office of Science and Technology Policy, February 22, 2013. https://obamawhitehouse.archives.gov/blog/2016/02/22/increasing-access-results-federally-funded-science.

Plan to Increase Access to Results of EPA-Funded Scientific Research, US Environmental Protection Agency, November 29, 2016. https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research.

Forum on Increasing Public Access to EPA Scientific Research Charter, US Environmental Protection Agency, April 17, 2017.

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EPA-Funded Research Publication Submissions in PubMed Central (PMC) Implementation Plan Version 1, 2 January 2018

I. Purpose

The Forum on Increasing Public Access to EPA Scientific Research was established by the Science and Technology Policy Council (STPC) to describe how the Agency will implement the "Plan to Increase Access to Results of EPA-Funded Scientific Research" (Plan). The purpose of this document is to describe how EPA intends to meet the requirement that the Agency make publicly available any research publications resulting from EPA-funded scientific research within one year of publication. This implementation plan provides instructions/guidance for intramural and extramural researchers to post their research publications to the National Institutes of Health PubMed Central digital repository (PMC). This plan applies to EPA funded research and focuses on intramural and extramural peer reviewed journal article manuscripts. This plan does not apply to scientific research not funded by EPA that may be cited in EPA assessments, rule-making, or peer-reviewed publications.

II. Background

The White House Office of Science and Technology Policy (OSTP) issued a memorandum to the heads of executive departments and agencies on February 22, 2013, with the subject, "Increasing Access to the Results of Federally Funded Scientific Research." The memorandum directed all federal agencies with over \$100 million of annual expenditures in research and development to make the peer-reviewed publications and associated digital data resulting from their research publicly available.

EPA selected PMC as the digital repository for EPA-funded research publications allowing the public to read, download, and analyze the Agency's journal articles at no charge. PMC is a full-text archive of journal literature submitted by participating journals and final manuscripts submitted by authors in conformance with public access policies. Further information about PMC is available at https://www.ncbi.nlm.nih.gov/pubmed/.

The EPA responded to the OSTP memorandum by issuing its Plan on November 29, 2016. The Plan established target dates for the Agency to make EPA-funded research publicly available as follows:

- Begin depositing prospective ORD intramural peer-reviewed research publications in PMC in 2016.
- Begin depositing prospective EPA (non-ORD) intramural peer-reviewed research manuscripts in PMC in 2017.
- Begin including relevant language requiring publications resulting from extramural research to be deposited in PMC in EPA-funded extramural solicitations in 2018.

EPA intramural and extramural researchers will be responsible for ensuring that their peer-reviewed publications resulting from EPA-funded scientific research are placed into PMC once the phase relevant to them is implemented. The requirement to post publications on PMC do not apply to journal articles published before the applicable implementation date.

Deposited manuscripts will not be displayed on PMC until 12 months after the article's publication date, per PMC default settings on publication release timing. Users may adjust release date timing in PMC to less than 12 months, depending on agreements with the publishing journal.

III. Submission Process Overview

The objective of this plan is to outline procedures for implementing EPA's commitment to provide the public, on a no-fee basis, increased access to peer-reviewed scholarly journal publications resulting from EPA-funded scientific research, consistent with applicable laws and policies, EPA's mission, and resource constraints. The plan does not apply to research publications generated prior to the implementation of the plan unless otherwise specified.

EPA researchers, or their programs and regions, will deposit final accepted, journal article manuscripts (i.e., that have incorporated peer review edits and any needed changes), hereafter referred to as the author manuscript, into PMC. To ensure the timeliness of these submissions, EPA will work toward utilizing the NIH Manuscript Submission system (NIHMS) no later than 30 days after the date of final publication. To clarify the relationship between PMC and NIHMS, PMC is

the repository for publications, and NIHMS is the mechanism/procedures by which manuscripts are entered.

Procedures governing the submission of extramural materials in NIHMS will be addressed separately in this plan. Submission of author manuscripts in NIHMS may be done by individual submission or bulk load submission. The individual submission process requires the submitter of the author manuscript to sign into NIHMS and upload the manuscript and supporting documents directly into the system. The bulk load process gathers multiple author manuscripts and supporting documents, prepares metadata, and then submits the information to NIHMS in an automated fashion on a nightly basis. EPA programs and regions will determine which submission process enables their researchers to best comply with this plan. Regardless of the manner of initial submission of a manuscript to PMC, the remaining steps are the same: submitters will perform both an initial review and approval and a final review and approval of the submitted documents in NIHMS (See Figure 1).

Figure 1.



Referring to Figure 1, with regard to individual submissions, the author will upload the manuscripts and perform the review and approval in one step. Upon completion of the conversion process, the authors will receive an email notice requesting final review and approval. If a submitter uploads a manuscript on behalf of the author, they will complete the upload and review of the submitted materials. Following this, the authors will receive two separate email notifications from NIHMS requiring them to access NIHMS – one to complete the initial approval of deposited materials, and a second email requiring them to complete the final review and approval of converted materials. Once both approvals are completed, the deposited manuscripts will be displayed on PMC upon expiration of the applicable embargo period.

In the case of bulk-load submissions, the submitter will receive two separate email notifications from NIHMS requiring them to access NIHMS – one to complete the initial review and approval of deposited materials, and a second email requiring them to complete the final review and approval of converted materials.

All EPA programs and regions will establish practices to identify and track author manuscript submissions to NIHMS regardless of the method of submission being used. At a minimum, EPA programs and regions will track the number of published manuscripts, the number of manuscripts submitted to NIHMS, and the number of manuscripts available on PMC for any period of time.

All EPA-funded, peer-reviewed, intramural and extramural research publication author manuscripts will be deposited in PMC. The only exception to author submission is when the direct deposit of published articles in PMC is accomplished by the publisher (known as indexed journals). To minimize duplicative submissions in NIHMS, researchers will check PMC to ensure their article has been deposited by the indexed journal prior to submitting the author manuscript to NIHMS. In instances when a published article and author manuscript are both deposited in NIHMS, the author manuscript submission process will be blocked and the published article will be displayed on PMC. If an indexed journal deposit does not exist, the author manuscript will be displayed on PMC. NIH performs the reconciliation between submissions of author manuscripts and published articles received from indexed journals during the conversion process. PMC is the archive of all EPA-funded peer-reviewed intramural and extramural research publications.

IV. Intramural peer reviewed scientific research publications

a. Office of Research and Development (ORD) - ORD author manuscripts published on or after January 2017 are deposited in NIHMS. ORD created a means of collecting author manuscripts in the Scientific and Technical Information Clearance System (STICS) and automatically transferring the materials to NIHMS via a batch process called the STICS bulk load process. ORD researchers provide author manuscripts to Technical Information Managers (TIMs) along with any supporting documents for entry in STICS. Once entered and identified as the author manuscript, STICS compiles the material, prepares the appropriate metadata, and automatically transfers the packages on a daily basis to NIHMS via the bulk load process. ORD will use the STICS bulk load process as the primary means of submitting materials to NIHMS. ORD accounts for the number of manuscripts submitted to NIHMS using STICS. In those rare instances when author manuscripts cannot be uploaded in STICS, researchers should use the

individual manuscript submission process in NIHMS and deposit their author manuscripts directly into the system. ORD Labs/Centers/Offices (LCOs) are responsible for tracking individual submissions.

- b. Non-ORD Programs and Regions Researchers in non-ORD programs and regions are required to deposit into NIHMS all author manuscripts accepted for publication after December 31, 2017. These programs and regions may develop clearance systems, practices, and methods for submission of manuscripts to NIHMS that best meet the specific needs of the program or region. Appendix C, Options for Submission of Non-ORD Program and Regional Intramural Research Publications to PMC, provides managers with four business processes that may be used to make deposits in NIHMS. Whatever procedure is adopted, it must result in conformance with the manuscript submission, tracking, and reporting requirements established by the Plan.
- c. Intramural publications with authors from multiple offices In all cases when there is an ORD co-author, the manuscript must be cleared for publication through STICS and whichever clearance process is developed and implemented by program offices and regions. In these cases, when there is an ORD co-author and an EPA co-author from outside ORD, EPA will take advantage of the STICS bulk load process and provide ORD the author manuscript and supporting documentation for entry into STICS and submission to NIHMS via the bulk load process. In instances of collaborations between non-ORD program or region authors, i.e., without an ORD co-author, the non-ORD authors will determine which organization will be responsible for submission of the author manuscript to NIHMS via whatever method is developed or employed by the non-ORD program or region. EPA researchers, or programs and regions, will work to ensure mitigation of duplicative submissions of the same author manuscripts to NIHMS.
- d. Intramural publications from collaboration with extramural EPA-Funded authors Non-ORD programs or regions will ensure author manuscripts produced from collaborations with extramural researchers are submitted to NIHMS in accordance with this plan. In accordance with the ORD Policies and Procedures Manual, Chapter 14, page 14.3-8, dated 20 September 2016, "ORD scientists who are co-authors in publications by outside entities, or where a non-ORD author is the lead, must have the product cleared through the ORD clearance process or the ORD scientist may not be listed as an author." This process creates the opportunity to leverage the bulk load process for submission of author manuscripts to NIHMS via STICS if the author manuscript and supporting documentation is provided to ORD. Determination of which party will deposit author manuscripts in

NIHMS is a matter to be resolved between the parties and the resolution must mitigate duplicative submission of the same manuscripts in NIHMS by multiple authors. EPA will abide by the terms and conditions of extramural grants or contracts for submission of author manuscripts in NIHMS.

- e. Intramural publications from collaborations with other federal government departments or agencies The framework of the collaboration among EPA and other government departments or agencies will determine which organization will deposit author manuscripts in NIHMS. However, ORD scientists must comply with ORD Clearance Policy for publication of scientific research products. As such, the opportunity for use of the bulk load process is available in cases when there are ORD coauthors. Non-ORD programs and regions will likewise ensure compliance with established clearance procedures for their organizations. To the extent possible, EPA and other federal departments and agencies should work together to mitigate duplicative submission of manuscripts in PMC. If the collaborating agency uses a repository other than PMC, submission of the article/manuscript in the other repository does not satisfy the requirements of the EPA plan.
- V. [Placeholder] Extramural scientific research publications Author manuscripts for all EPA-funded, peer-reviewed research publications will be deposited in PMC. NIHMS is the manuscript submission system for all materials deposited in PMC and as such will be used for all submissions of extramural research manuscripts. Deposits of extramural research manuscripts in NIHMS require identification of all funding used to support the research publication. Consistent with the terms of EPA grant and contract agreements, EPA retains the right to require extramural researchers to provide author manuscripts to EPA upon acceptance of the manuscript for publication. The requirement to have extramural author manuscripts deposited in PMC via NIHMS will be specified in all EPA grant and contract agreements. EPA will abide by the terms and conditions of extramural grants or contracts for submission of author manuscripts in NIHMS.
- VI. Posting Publications in PMC NIHMS will be used for submission of authors manuscripts to PMC. When an article completes peer review and is accepted by a journal, the author will retain the copy of the author manuscript, which contains the incorporated peer reviewed edits and changes, and submit it to NIHMS. Regardless of the manner used to submit a manuscript in NIHMS (e.g., bulk load process or individual submission), the submitter must complete two separate reviews and approvals in NIHMS (e.g., the initial review and approval and the final review and approval). Both of these reviews need to be completed before

a manuscript can be displayed on PMC. The appendices illustrate the steps required to complete the initial review and approval of a submitted manuscript.

VII. Tracking and Reporting - EPA programs and regions are responsible for tracking the status of both intramural and extramural publications. EPA will develop and implement procedures to collect the number of published manuscripts, the number of manuscripts submitted to NIHMS, and the number of manuscripts available on PMC for any time period. Programs and regions will determine the method for collection and tracking of their publication statistics. Tracking is intended to roll up from the program and regions for subsequent EPA-level reporting purposes.

VIII. Implementation Plan Review – This implementation plan will be periodically reviewed by the Public Access Forum and revised as needed.

IX. Glossary.

- Author Manuscripts The version of a paper that has been peer reviewed and accepted for publication by the journal including all changes made during the peer review process
- Bulk Load Process An automated batch process that can be used to deposit Author Manuscripts in NIHMS
- *Embargo* Time period (in months) established by the publisher restricting release of the manuscript
- Indexed journals Publishers who deposit articles in PMC
- *Individual Deposit* The process that individual authors or researchers use to deposit manuscripts in NIHMS
- NCBI National Center for Biotechnology Information provides access to biomedical and genomic information
- NIHMS NIH Manuscript Submission system facilitates acceptance of manuscripts for inclusion in PMC
- Non-Indexed journals Publishers who do not deposit articles in PMC
- **PI** Principal Investigator is the intramural researcher or extramural awardee whose work is being deposited in PMC and may serve as both the submitter/reviewer
- **PMC** PubMed Central is the National Library of Medicine's full text journal archive, which provides public access to papers at no cost
- PMCID Identifier assigned to full-text record in PMC
- Reviewer Person responsible for approving initial deposit in NIHMS and then approving manuscript for release in PMC

- *STICS* Scientific and Technical Information Clearance System is ORD's research product clearance system
- Submitter Individual who deposits files in NIHMS
- TIM Technical Information Manager is the person who can upload manuscripts, initiate clearances, and complete and maintain records in STICS

X. REFERENCES/RESOURCES

 $\underline{https://obamawhitehouse.archives.gov/blog/2013/02/22/expanding-public-access-results-federally-funded-research}$

https://www.epa.gov/open/plan-increase-access-results-epa-funded-scientific-research

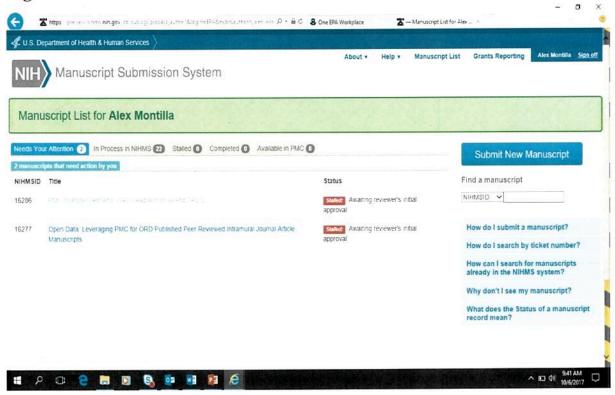
https://www.ncbi.nlm.nih.gov/pubmed/

APPENDIX A

Process Instructions for Posting Publications in NIHMS Using the STICS Bulk Load Process

NIHMS may be accessed in three ways: by using the link provided in email notices; by accessing NIHMS directly from the internet; or by using the link on PubMed Central on ORD@Work. When a user signs in to NIHMS for the first time, they are taken to a Preferences page to set up their profile (e.g., name, contact information). For all subsequent visits to NIHMS, the user is taken directly to the Manuscript List (Figure A1) shown below.

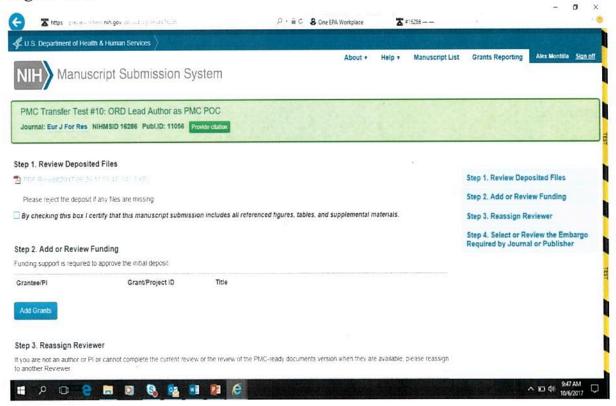
Figure A1.



If you are an author or submitter and received an email asking you to sign in and review a manuscript submission that was initiated on your behalf, click on the access link in the email to sign in, and you will be directed to the manuscript awaiting your review. Beginning at the Manuscript List, select the manuscript you wish to review by clicking on the title of the manuscript. The manuscript page will now appear (Figure A2). Here a user reviews the deposited files by clicking on the PDF link that appears on the screen. The PDF Receipt summarizes the information

that the submitter entered into the system and merges the files into one viewable document for your approval. This review is performed to ensure the completeness of the deposited materials and make certain all files are present and complete. If all of the files are present and complete, click the certification box. A check mark will appear in the box if done correctly.

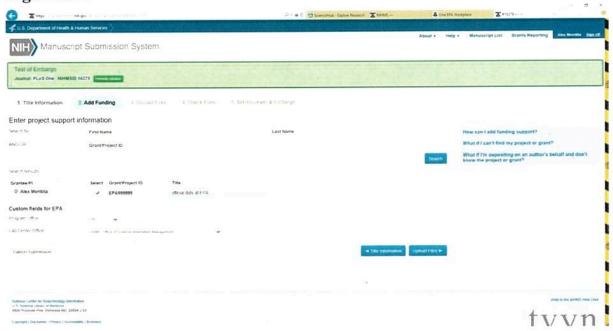
Figure A2.



Click the "Add Grants" button (Figure A2 above) to review funding information. The funding information will appear on a new page (Figure A3 below). At this point, it is important to make a distinction between intramural and extramural users and submissions. For all EPA intramural researchers who sign in to NIHMS using their Smart Card and PIN, the authentication process will use those credentials to identify the user as an EPA intramural researcher. In this case, the Grant/Project ID field will be populated with the following funding string: EPA999999. EPA intramural researchers only need to click on the "Select" box provided to confirm the submission pertains to EPA intramural research. A check will appear once the box is clicked as shown in Figure A3 below. Extramural researchers will have to enter the appropriate Grant/Project ID number and then select all applicable funding sources in the fields provided on the screen. If extramural researchers

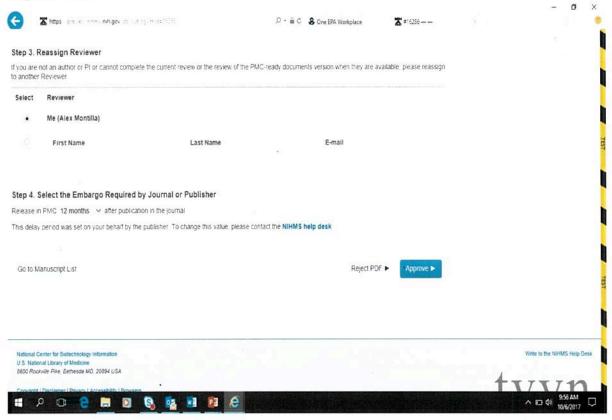
have created an NCBI account and listed their funding sources, then a search can be performed in NIHMS to populate the screen with the applicable information. All relevant funding sources must be identified and selected for extramural research publications.

Figure A3.



Once the funding information has been reviewed and selected, complete the fields customized for EPA. Use the drop-down arrows to select the EPA Program or Regional Office associated with the manuscript and the Lab, Center, or Office within the office from the drop-down menus. If the manuscript submission was initiated on your behalf, click "Save" at the bottom of the screen. Otherwise, proceed to upload files. Please note the Save button will appear in place of the Upload Files button in Figure A3 above and will return you to the previous menu (Figure A2). The last two steps of the initial review will be performed on this page. Scroll down to the bottom of the screen to view Step 3 and Step 4 (Figure A4). If applicable, another reviewer can be specified. Regardless of who performs the initial review, the reviewer must be able to authoritatively agree to the conditions in the NIHMS Submission Statement (Figure A6 below). If designation of another reviewer isn't required, then go to Step 4 (Figure A4). All submissions made through the bulk load process will have a 12-month embargo period specified in Step 4 of Figure A4 by default. Once the embargo period has been entered, the "Approve" button can be selected at the bottom of the screen (Figure A4).

Figure A4.



Upon clicking the "Approve" button, a prompt will appear stating, "You must certify that the manuscript submission includes all referenced figures, tables, and supplemental materials" (Figure A5). If all of the materials submitted in NIHMS are confirmed to have been uploaded in the system, then Click "OK" and proceed to the NIHMS Submission Statement. Otherwise, return to the Manuscript and upload any missing materials. EPA-funded researchers must ensure the completeness, quality, and integrity of the scientific material posted on PMC; NIH will reject incomplete submissions.

Figure A5.

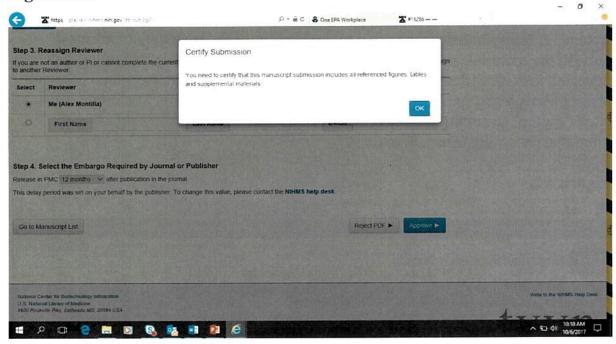
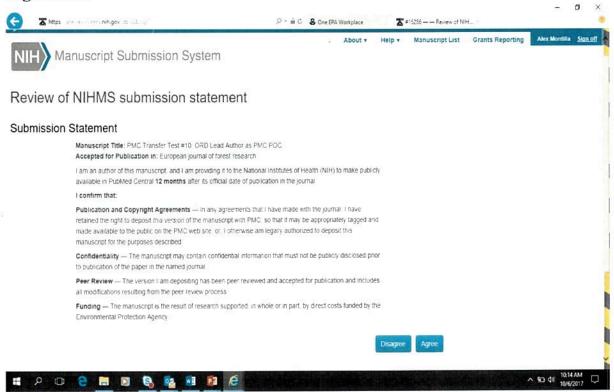
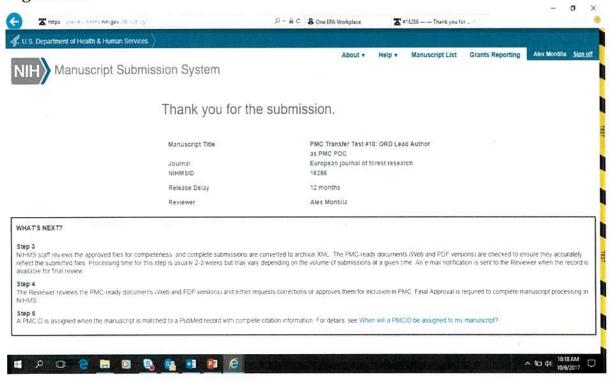


Figure A6.



The NIHMS Submission Statement (Figure A6) is the last step in the initial review process. All reviewers must read the submission statement carefully. In the statement, the submitter is attesting to: authorship of the material; authority to publish the material; recognition of the period of embargo; peer review of the material; and identification of all funding sources. If the submitter can affirmatively attest to the conditions of the NIHMS Submission Statement, then click "Agree" to submit the material. NIHMS will confirm the submission immediately on the screen (Figure A7).

Figure A7.



Upon completion of the initial approval in NIHMS, NIH will complete the conversion process, which includes reconciliation of the submitted materials and documents submitted by publishers (indexed journals), as well as reformatting the files into XML for display on PMC. If the published journal article is discovered to have been deposited in PMC by the publisher, the journal article will be displayed on PMC. If the journal article has not been deposited in PMC by the publisher, the author manuscript will be displayed on PMC.

The conversion process may take several weeks to complete. Upon completion of the conversion process, an email notice will be sent to the PMC POC requesting the completion of the final review and final approval.

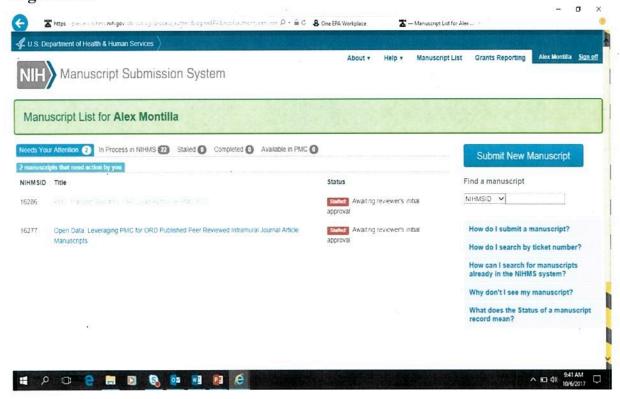
The final review and approval consists of accessing NIHMS in the same manner described above for the initial review. The final review and final approval is conducted to ensure the conversion process did not negatively alter the content in the submitted materials. During initial review, the submitter has already asserted that the submitted package was complete. Therefore, the final review and approval concentrates on the results of the format conversion to ensure readability and proper conveyance of the information. Once these considerations have been addressed and satisfied, click the final approval button. PMC will display the manuscript once the 12-month embargo period has expired assuming the reconciliation process did not discover a deposited journal article. An email notice will be sent to the submitter notifying them when the material is available to view on PMC.

APPENDIX B

Process Instructions for Posting Publications in NIHMS via Individual Submission

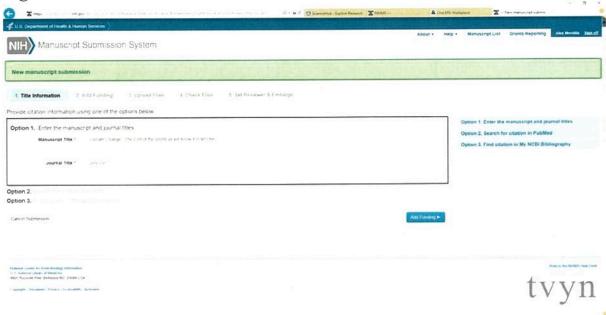
Individual submissions of manuscripts in NIHMS can be performed directly in the system by authors. Once the author has logged into NIHMS, simply click the Submit New Manuscript button in the right column of the Manuscript List screen (Figure B1).

Figure B1.



The New manuscript submission page will now appear (Figure B2). Here a user enters the manuscript title and the journal title in one of three ways: by directly typing the entry into NIHMS; searching for the citation in PubMed; or finding the citation in My NCBI Bibliography. Once the manuscript title has been entered along with the journal title, click on the Add Funding button at the bottom of the script (Figure B2).

Figure B2.

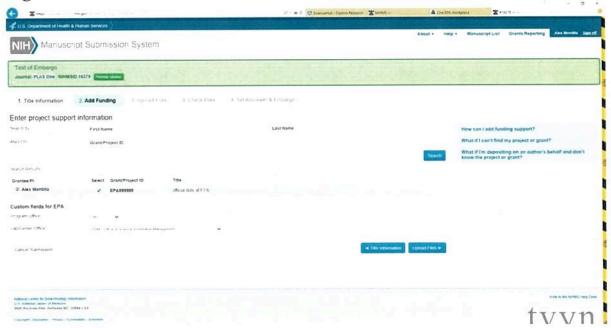


The funding information will appear on a new page (Figure B3 below). At this point, it is important to make a distinction between intramural and extramural users and submissions. For all EPA intramural researchers who sign in to NIHMS using their Smart Card and PIN, the authentication process will use those credentials to identify the user as an EPA intramural researcher. In this case, the Grant/Project ID field will be populated with the following funding string: EPA999999. EPA intramural researchers only need to click on the "Select" box provided to confirm the submission pertains to EPA intramural research. A check will appear once the box is clicked as shown in Figure B3 below. Extramural researchers will have to enter the appropriate Grant/Project ID number and then select all applicable funding sources in the fields provided on the screen. If extramural researchers have created an NCBI account and listed their funding sources, then a search can be performed in NIHMS to populate the screen with the applicable information. All relevant funding sources must be identified and selected for extramural research publications.

Once the funding information has been reviewed and selected, complete the fields customized for EPA. Use the drop-down arrows to select the EPA Program Office or Region associated with the manuscript and the corresponding Lab, Center, or Office within the Program Office from the drop-down menus. These fields were added to NIHMS to more accurately represent research publications by the respective EPA organizations sponsoring or participating in the research. Please

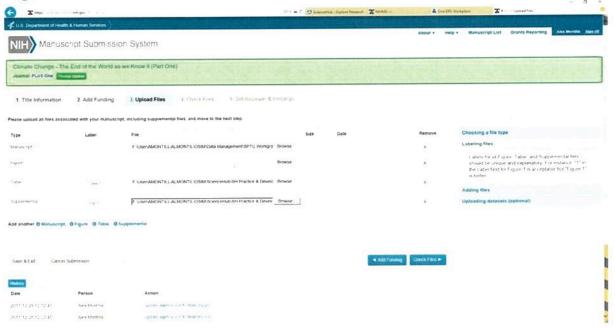
note only one EPA organization can be specified. Proceed to upload files by clicking the Upload Files button on the bottom of the screen (Figure B3).

Figure B3.



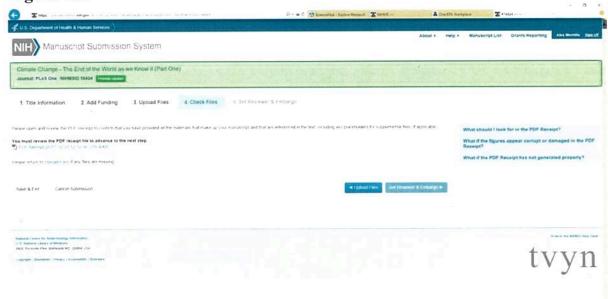
The Upload Files screen (Figure B4) facilitates the submission of the manuscript, figures, tables and supplemental document files in NIHMS. Instructions on labeling and adding files are available on the right-hand column of the screen. It is important to ensure that all figures, tables and supplemental documents referenced within the manuscript are identified and uploaded to NIHMS. Doing otherwise will result in missing files and will require additional steps to upload missing files later. The author will need to work with the agency admin to upload any missing files not uploaded during this step. Navigate to the Manuscript row, and click the Browse button. Windows will open, and from there, navigate to the location of the manuscript and select the desired file. Once selected, the path to the manuscript file will displayed in the space provided. Do the same thing for the Figure, Table, and Supplemental documents. Please note all Figure, Table, and Supplemental documents must have unique labels (e.g. Figure 1, Table 1, and Sup 1).

Figure B4.



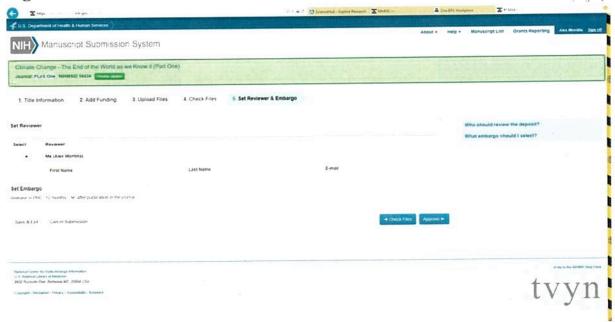
Once all of the files have been uploaded, click the Check Files button at the bottom of the screen. A small box or window will momentarily open and close, and then the screen will refresh revealing a progress bar. Once the uploaded materials have been submitted, a PDF Receipt will appear on the screen (Figure B5). Click on the PDF Receipt link to open the file. Another window will open revealing the Manuscript Information, files uploaded, and documents submitted. Scroll through the contents of the PDF Receipt and ensure all of the submitted materials are accounted for within the document. Once the review is completed, close the window. Upon closing the window, the Set Reviewer & Embargo button at the bottom of the screen will become active allowing you to navigate to the next screen. Click the Set Reviewer & Embargo button.

Figure B5.



The Set Reviewer & Embargo screen (Figure B6) enables you to select another reviewer of the submitted materials and enter the embargo period. The embargo period is typically 12 months from the data of last publication. However, embargo periods may be shorter depending on the journal or date of last publication. Select the correct embargo period using the drop-down menu, and then click the Approve button at the bottom of the screen.

Figure B6.



Upon clicking the "Approve" button, a prompt may appear stating, "You must certify that the manuscript submission includes all referenced figures, tables, and supplemental materials" (Figure B7). The prompt typically appears when only one file is uploaded in NIHMS. If NIHMS recognizes multiple files (e.g. manuscript, figure, table and supplemental), the prompt will not be displayed, and you will be taken to the NIHMS Submission Statement (Figure B8). If the prompt (Figure B7) does appear, simply confirm all materials have been submitted in NIHMS, and click "OK" to proceed to the NIHMS Submission Statement. Otherwise, return to the Manuscript and upload any missing materials. EPA-funded researchers must ensure the completeness, quality, and integrity of the scientific material posted on PMC; NIH will reject incomplete submissions.

Figure B7.

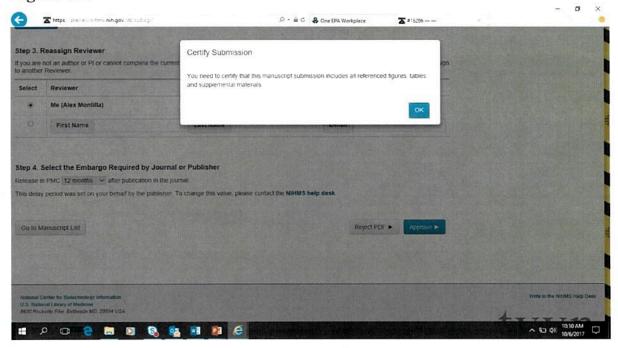
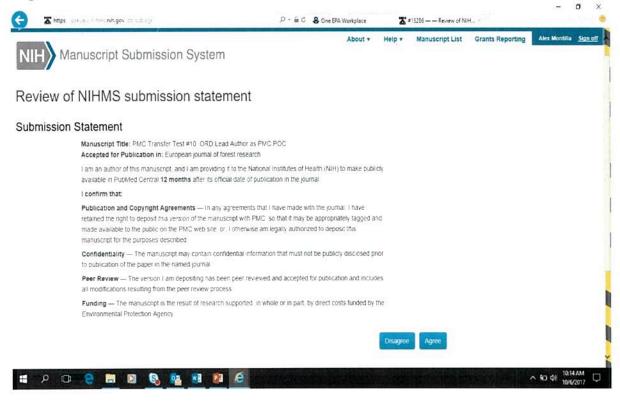
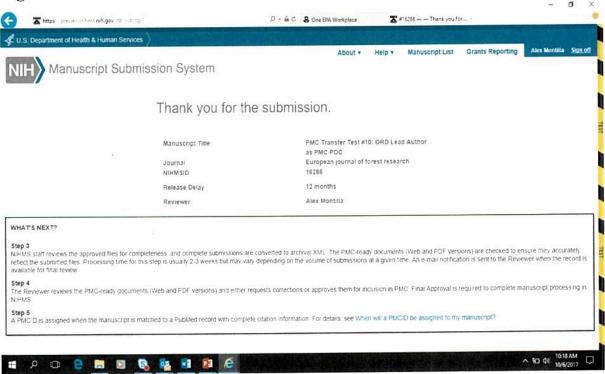


Figure B8.



The NIHMS Submission Statement (Figure B8) is the last step in the initial review process. All reviewers must read the submission statement carefully. In the statement, the submitter is attesting to: authorship of the material; authority to publish the material; recognition of the period of embargo; peer review of the material; and identification of all funding sources. If the submitter can affirmatively attest to the conditions of the NIHMS Submission Statement, then click "Agree" to submit the material. NIHMS will confirm the submission immediately on the screen (Figure B9).

Figure B9.



Upon completion of the initial approval in NIHMS, NIH will complete the conversion process, which includes reconciliation of the submitted materials and documents submitted by publishers (indexed journals), as well as the reformatting of the files into XML for display on PMC. If the published journal article is discovered to have been deposited in PMC by the publisher, the journal article will be displayed on PMC. If the journal article has not been deposited in PMC by the publisher, the author manuscript will be displayed on PMC.

The conversion process may take several weeks to complete. Upon completion of the conversion process, an email notice will be sent to the submitter requesting the completion of the final review and final approval.

The final review and approval consists of accessing NIHMS in the same manner described above for the initial review. The final review and final approval is conducted to ensure the conversion process did not negatively alter the content in the submitted materials. During initial review, the submitter has already asserted that the submitted package was complete. Therefore, the final review and approval concentrates on the results of the format conversion to ensure readability and proper conveyance of the information. Once these considerations have been addressed and satisfied, click the final approval button. PMC will display the manuscript once the 12-month embargo period has expired assuming the reconciliation process did not discover a deposited journal article. An email notice will be sent to the submitter notifying them when the material is available to view on PMC.

APPENDIX C

Options for Submission of Non-ORD Program and Regional Intramural Research Publications to PMC

- Option 1: Programs and Regions make their authors responsible for submitting manuscripts
- Option 2: Programs and Regions designate someone in their office to submit manuscripts created in their organization
- Option 3: Programs and Regions fund a technical information manager (TIM) in ORD to submit their manuscripts
- Option 4: EPA develops an electronic system for Programs and Regions to submit manuscripts (longer term)

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